Summary of th Invention of the Pres nt Application:

The invention of the present application provides a composition and method for determining compliance with a medication regimen. This composition and method is rapid, simple, and inexpensive. In one embodiment, it includes an orally administrable composition in combination with at least one visual marker. This marker is present in a form and amount sufficient to cause a coloration of at least a portion of the oral and/or pharyngeal cavity of a patient. In various embodiments of the invention, by way of non-invasive observation of this coloration of the oral/pharyngeal cavity, one may obtain information regarding patient compliance with a medication regimen, such as whether the medication has been taken, the time elapsed since the medication was last taken, whether it is time for another dose of medication, etc. Thus, the present invention is very rapid and simple as opposed to more invasive, tedious, and complicated monitoring methods, of the prior art such as the analysis of urine and stool samples.

Claim Rejections 35 U.S.C. § 102:

The Examiner has rejected claims 15, 18, 19, 21, and 22 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,200,604 (the Pather et al. '604 patent). The Examiner states that Pather et al. discloses an orally administrable composition containing a coloring agent such as carmine, F.D.&C. dyes, etc. The Examiner further states that coloring agents used in orally administrable compositions act as markers by coloring or staining a portion of the oral/pharyngeal cavity. Thus, according to the Examiner, the present application is anticipated by the Pather et al. '604 patent. Applicants respectfully disagree.

The Pather et al. '604 patent is directed to a sublingual buccal effervescent. Applicants note that the Examiner cites the language in the Pather et al. '604 patent at col. 5, lines 1-6 and lines 26-28 for support. Applicants further note that while the Pather et al. '604 patent does list various coloring agents, including carmine, in an oral composition, such coloring agents find their use solely for the purpose of imparting a particular color to the composition of the Pather et al. '604 patent. They have no purpose and indeed teach no purpose beyond that. In other words, the coloring agents are used to provide an aesthetic, cosmetic characteristic (color) to the composition, much like a flavoring agent would be used to make the composition more palatable. There is no teaching in the Pather et al. '604 patent that such coloring agents function as anything but as a superficial component for aesthetic and cosmetic purposes. That is, they are essentially "throw-away" components with respect to the therapeutic action provided by the composition. They certainly do not teach the invention utilizing a marker in a form and sufficient amount to cause coloration of a patient cavity for subsequent visual observation.

Applicants submit that the use of coloring agents as "throw-away" components in the Pather et al. '604 patent is very apparent when one considers the disclosure of column 5, lines 1-6 when taken in view of the paragraph at column 4, lines 52-58 of the Pather et al. '604 patent. The paragraph concerning coloring at column 5, lines 1-6 is introduced earlier in the paragraph of column 4, lines 52-58 as a mere list of ingredients which may be included in the composition. These ingredients may include "glidants, lubricants, binders, sweetener, flavoring, and coloring components." The subsequent paragraphs go on to simply list examples of these

coloring ingredients. However, there is no indication that the coloring agent plays any significant role in the composition of the '604 patent, nor does the '604 patent teach that the coloring agent is present in a form and amount sufficient to stain the oral/pharyngeal cavity for subsequent visual observation to determine compliance with a medication regimen. In contrast, the coloring agent of the composition of the present application is what allows an observer to determine compliance, duration since last medication, remaining time until next medication, etc. There simply is no teaching in the Pather et al. '604 patent by which one of skill in the art may use the composition disclosed therein to obtain such information.

Further, as mentioned above, Applicants assert that there is absolutely no teaching in the Pather et al. '604 patent that the coloring agent is provided in a form and sufficient amount to cause coloration of a part of the oral and/or pharyngeal cavity such that it is used as a marker to determine whether a patient has complied with a medication regimen, as is recited in the claims of the present application. First, the composition of the Pather et al. '604 patent is taught as having a wholly different purpose than that of the present application. Reference to the entire Pather et al. '604 patent makes it quite clear that the purpose of the composition of that reference lies in that it includes an effervescent to promote absorption of the medicament directly into the oral cavity. Nowhere does the Pather et al. '604 patent discuss or teach that the use of the coloring agent is part of a method for monitoring patient compliance. Rather, as described above, the coloring agent of the Pather et al. '604 patent is merely used to impart an aesthetic, cosmetic quality to the composition. Second, the amount of coloring agent in the prior art composition, while providing color to the tablet,

does not provide an amount sufficient to cause significant coloring such that it is visually observable after ingestion to determine compliance, and other issues, such as the duration since the last medication. In the Pather et al. '604 patent, the amount of coloring agent in the composition is recited at col. 5 as 0.1 - 3.5 weight percent of the total composition. Applicants assert that this is not a sufficient amount to cause an observable coloration in a patient in order to determine compliance. Any instantaneous, minor coloring presented immediately after the prior art composition is consumed would be so short-lasting or fleeting that to even be possibly observed, it would have to be done so immediately. That is, the observer might as well be present to dispense the medication. As may be appreciated, this defeats the entire purpose of the invention. Therefore, the cited '604 patent does not in any way teach or suggest the invention as claimed nor would it be usable for the invention.

In view of the above, Applicants respectfully request a withdrawal of the rejection of claims 15, 18, 19, 21, and 22 under 35 U.S.C. § 102(e).

Claim Rejections 35 U.S.C. § 103:

The Examiner has rejected claims 1-14, 16, 17, 20, and 23-27 under 35 U.S.C. § 103(a) as being unpatentable over the Pather et al. '604 patent in view of U.S. Patent No. 5,776, 783 (the Kell '783 patent). The Examiner states that the Kell '783 patent teaches the use of a marker for monitoring patient compliance with medication prescriptions wherein the marker is added to a medical formulation by mixing homogeneously or interspersing throughout the formulation, or as a film or coating on a tablet or capsule for introduction into the body of a patient (citing col. 4, lines 19-22, lines 37-41, and lines 47-53). The Examiner suggests that it would have been obvious

to one of ordinary skill in the art at the time the invention was made to have provided the coloring agent of Pather et al. as a coating or film or interspersing it throughout the formulation or composition as taught by the Kell '783 patent for introduction into the body of a patient. Applicants respectfully disagree.

Applicants submit that the Kell '783 patent discloses a composition and method for tracking compliance by using markers in association with medications wherein marker concentrations can be measured invasively in a patient's urine. (See col. 4, lines 47-53.) This is a significant and dispositive difference that would not be overlooked by a person of ordinary skill in the art. The Kell reference flies in the face of the purpose of the patent. There is no discussion in the Kell '783 patent of using coloring agents as markers in an amount sufficient for staining of the oral and/or pharyngeal cavity. As described above, it is Applicants' assertion that the use of coloring agents as markers for staining of the oral and/or pharyngeal cavity for subsequent visualization to determine patient compliance is also not disclosed by the Pather et al. '604 patent. Thus, Applicants respectfully assert that the combination of the Pather et al. '604 patent with the Kell '783 patent does not disclose each and every claimed limitation in the claims of the present application.

Further, as discussed above, the Kell '783 patent clearly discloses monitoring methods involving measuring markers in a patient's urine. Analysis of urine is a process that is time consuming, intrusive, requires scheduling, and requires the presence of a trained technician. These are the very drawbacks of current monitoring methods, described in the "Background of the Invention" section of the present application, that the present invention eliminates. In fact, urine analysis was one of the

prior art monitoring methods that was discussed in the present application as wholly different than the compliance monitoring composition and method of the present invention. The present invention is rapid, simple, and inexpensive in that it is simply performed by observing the oral/pharyngeal cavity some time after ingestion for coloration in order to determine compliance.

Further, Applicants assert that even were one to combine the Pather et al. '604 patent and the Kell '783 patent, the combination does not teach the invention. In particular, as described above, the Pather et al. '604 patent discloses a sublingual buccal effervescent, of which may include a coloring agent merely to impart color to the ingestable pill, capsule, etc. The Kell '783 patent discloses a method of monitoring patient compliance with a medical regimen by testing the urine of a patient. Applicants thus respectfully assert that even if one were to attempt to detect the coloring agent of the Pather et al. '604 patent, it could not be detected in the urine by the method disclosed by the Kell '783 patent, since such coloring agent would not be detectable in a patient's urine. Nor would such a coloring agent be visually observable in a patient's urine.

Further, Applicants note that various dependent claims rejected by the Examiner are obviously not taught by the Pather et al. '604 or Kell '783 patents or the combination of the two. These include observation of the oral/pharyngeal cavity under fluorescent light (claims 5, 6, 13, 14, 26, 27); the use of multiple markers (claims 10-14 and 23-27); and the half-life of the marker being equal to the half-life of the composition (claim 20).

Thus, Applicants respectfully assert that neither the Pather et al. '604 patent, nor the Kell '783 patent disclose or render obvious the invention of the present application. Further, Applicants assert that the combination of the Pather et al. '604 patent with the Kell '783 patent fails to disclose or render obvious the entire claimed invention of the application. Applicants therefore respectfully request a withdrawal of the rejection under 35 U.S.C. § 103.

Conclusion:

For the foregoing reasons, Applicant submits that all claims are patentable and a Notice of Allowance is respectfully requested.

Applicants' petition for a one month extension of time under 37 CFR 1.17(a)(1) with accompanying fee is included with this response. If any additional fee or surcharges are deemed due, please charge same or credit any overpayment to deposit account no. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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